REMARKS/ARGUMENTS

In response to the Office Action mailed April 20, 2006, Applicants amend their application and request reconsideration in view of the amendments and following remarks. In this amendment, Claim 1 is amended, no claims have been cancelled without prejudice and no claims have been added so that Claims 1-3, 16 and 17 are currently pending. No new matter has been introduced.

Claims 1-3, 16 and 17 were rejected as being unpatentable over U.S. Patent Number 5,833,651 to Donovan et al. (Donovan) in view of U.S. Patent Number 6,872,225 to Rowan et al. (Rowan). This rejection is respectfully traversed.

The present invention, as claimed in amended independent Claim 1, is directed to a local drug delivery device which comprises a medical device for implantation into a treatment site of a living organism, a layer including a rapamycin, in therapeutic dosages, incorporated in a polymeric matrix and affixed to the medical device for the treatment of reaction by the living organism caused by the medical device or the implantation thereof, and a biocompatabile water soluble powder configured to prevent the at least one agent from separating from the medical device prior to implantation. The biocompatabile water-soluble powder being applied to the outermost surface of the polymeric matrix. This facilitates delivery of the device as is explained in detail in the specification.

Donovan discloses a stent having a polymeric composition affixed thereto. The polymeric composition comprises fibrin. The stent also comprises a virus associated with the polymeric coating. In some embodiments, a powder form of heparin may be affixed to the stent during the polymerization process and additional thrombin and fibrinogen can then be applied on a coating over the heparin.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness.

> "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria."

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

> "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1074). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

It is respectfully submitted that Donovan fails to teach or suggest all of the claimed limitations. It is very clear that Donovan discloses a powder form of heparin

placed on a stent, but it is not the outermost layer as in the claimed invention. Thus, the elements are not taught by Donovan. Rowan also fails to disclose this arrangement. Since neither reference discloses or even suggests this unique configuration, the present invention cannot be considered to be obvious in light thereof. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

In addition, the powdered form of heparin is added during the polymerization process and covered with thrombin and fibromogen. Clearly, this is not configured to prevent the elements from sticking to themselves as claimed in the present invention. Once the powder is added to the polymer solution it is not serving its protective function, but rather a therapeutic function.

Applicant's attorney would like to thank the Examiner for her kind help and attention to this matter.

A favorable action is earnestly solicited.

Respectfully submitted,

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